Boston Scientific

MAR - 7 2008

510(k) Summary

General Information

Category:	Comments:
Sponsor:	Boston Scientific Corporation 2710 Orchard Parkway San Jose, Ca 95134
Correspondent:	Cindy Morrow Principal Regulatory Affairs Specialist Boston Scientific Corporation 2710 Orchard Parkway San Jose, CA 95134
Contact Information:	E-mail: morrowc@bsci.com Phone: (408) 895-3931 Fax: (408) 895-2202
Device Common Name:	Cardiac Introducer Sheath
Device Proprietary Name	Convoy Advanced Delivery Sheath Kit
Device Classification	21 CFR §870.1340 Product Code: DYB
Predicate Device	Convoy Advanced Delivery Sheath Kit
Predicate Device Manufacture(s)	Boston Scientific Corporation
Predicate Device Proprietary Name(s)	Convoy Advanced Delivery Sheath Kit
Predicate Device Classification	21 CFR §870.1340
Predicate Device Classification #	Class II

Date Summary Prepared

November 20, 2007

Boston Scientific

Description of the Predicate Device

The Boston Scientific (BSC) Convoy Advanced Delivery Sheath Kit is identical to the BSC Convoy Advanced Delivery Sheath Kit described in K013866, K022067, and K034061 approved on December 14, 2001, September 11, 2002, and January 30, 2004 respectively.

The Convoy Advanced Delivery Sheath Kit consists of: (1) a disposable Introducer Sheath, (2) a Vessel Dilator and (3) Guidewire with Guidewire Introducer. These devices are designed for the introduction of various types of cardiovascular catheters to the heart. The Introducer Sheaths are constructed in a range of curve reach configurations, diameters and lengths to respond to physician preferences. The Introducer Sheath configurations covered under the subject 510(k) Premarket Notification include 8.5 F and 9.5 F diameters, angles ranging from 0° - 180°, radius of curvatures ranging from 0.6" - 1.75", lengths of 60 cm - 101.5 cm, and may be configured with either one, two or three curves in a single or dual plane.

The Convoy Advanced Delivery Sheath Kit is intended to facilitate the intracardiac placement of interventional devices.

Comparison to Predicate Device

	Predicate Device	Modified Device
510(k) Reference	K034061, K022067, and K013866	Current Submission
Intended Use	Intracardiac Placement of Interventional Devices	Same
Device Description	Intracardiac Introducer Sheath	Same
Single Use?	Yes	Same
EO Sterilized?	Yes	Same
Device Manufacturer	Boston Scientific Corporation	Same
Regulatory Class	II	Same
Device Classification	21 CFR §870.1340	Same

Change to Labeling Being Effected

A new contraindication has been added to the labeling:

Insertion of the Convoy Advanced Delivery Sheath is contraindicated from the femoral approach in patients who have vena cava embolic filter devices, or from a leg with a known femoral thrombus.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 7 2008

Ms. Cindy Morrow
Principal Regulatory Affairs Specialist
Boston Scientific Corporation
2710 Orchard Parkway
San Jose, CA 95134

Re: K072719
Trade/Device Name: Convoy Advanced Delivery Sheath Kit
Regulation Number: 21 CFR 870.1340
Regulation Name: Introducer, Catheter
Regulatory Class: Class II
Product Code: DYB
Dated: December 7, 2007
Received: December 10, 2007

Dear Ms. Morrow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Bachman

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072719

Device Name: Convoy Advanced Delivery Sheath Kit

Indications for Use:

The Convoy Advanced Deliver Sheath Kit is intended to facilitate the intracardiac placement of interventional devices.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K072719

(Posted November 13, 2003)